

REMARKS

Applicant hereby replies to the Final Office Action dated January 2, 2007 within two months. Thus, Applicant requests an Advisory Action, if necessary. Claims 1-22 and 25 were pending in the application and the Examiner rejects claims 1-22 and 25. Reconsideration of the pending claims is requested. The amendments are adequately supported in the originally-filed specification, drawings and claims. No new matter is added in this Reply.

The Examiner objects to the drawings under 37 CFR § 1.83(a) because the “spring” of claim 26 is not shown in the drawings. Applicant asserts that claim 26 has been withdrawn from consideration, so this objection is now moot.

The Examiner rejects claims 14-16 under 35 USC § 112 because of antecedent basis issues. Applicant amends claims 14 and 15 to correct the antecedent basis, so the rejection of claims 14-16 are now moot.

Applicant also amends the claims to remove the “configured to” language of concern by the Examiner.

The Examiner rejects claims 1, 3, 4, 6, 11-13, 17, 20, 21 and 25 under 35 USC § 102(b) as being anticipated by Fletcher, U.S. Patent No. 6,050,998 (“Fletcher”). Applicant respectfully traverses this rejection.

The Fletcher device includes a loop device which must enter and exit each object (or bone portion) being fixated while also traveling through an extended canal in each object. As such, the Fletcher device requires an entrance hole, exit hole and an extended canal in each bone portion, thereby substantially increasing, for example, the risk of infection, additional damage to the bone, loss of bone integrity, additional time in surgery and additional healing time. Moreover, the “cap” portion of the Fletcher device is connected to both ends of the wire, thereby increasing the size of the cap portion, and increasing the number of components adhering to the cap portion, thereby creating additional problems for burying the cap portion within the bone. As such, a larger hole is needed to bury the cap portion and the other end of the wire exits from the burying hole and outside of the bone, thereby again increasing risk of infection additional damage to the bone, loss of bone integrity, additional time in surgery and additional healing time. In contrast, the presently claimed invention does not require an additional exit hole, a canal, a loop exiting the bone, nor additional components on the cap. Accordingly, Fletcher does not disclose or suggest at least “a head component having cutting threads, said head component

inserted into, and terminating within, one of said objects,” as similarly recited in independent claims 1, 11 and 17.

Applicant asserts that dependent claims 3, 4, 6, 12-13, 20, 21 and 25 variously depend from independent claims 1, 11 and 17, so claims 3, 4, 6, 12-13, 20, 21 and 25 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner rejects claims 11, 12 and 17-20 under 35 USC § 102(b) as being anticipated by Goble, et al., U.S. Patent No. 5,702,397 (“Goble”). Applicant respectfully traverses this rejection.

Applicant asserts that Goble is limited to forming a tunnel, inserting a bone anchor, inserting a suture through the bone anchor and attaching the suture to the ligament graft to allow the graft to be pulled through the bone anchor and then clamped to the suture. The Goble device allows the suture and graft to travel through the bone anchor and does not apply pressure between two portions of a bone. Moreover, the suture is not affixed to the anchor prior to inserting the anchor into the bone and the pressure applied to the suture is due to the pulling by the ligament graft, and not by any type of head component or cap. Additionally, the Goble anchor must be rotated to secure its cap into its anchor portion. Such rotation may disrupt or injure other portions of the body, along with spiraling fluid and unwanted materials through the canal. In contrast, the presently claimed invention includes a cap which translates along the flexible wire. Accordingly, Goble does not disclose or suggest at least “flexible wire is affixed to said head component” prior to insertion into the bone, “said middle wire portion extends across an interface between said first bone portion and said second bone portion”, “a cap which mates with said second end of said flexible wire by translating along said flexible wire while restricting reverse translational movement”, nor a system which “apply pressure between said first bone portion and said second bone portion,” as similarly recited by independent claims 11 and 17.

Applicant asserts that dependent claims 12 and 18-20 variously depend from independent claims 11 and 17, so claims 12 and 18-20 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner rejects claims 14-16 under 35 USC § 102(b) as being anticipated by McLaren, U.S. Patent No. 5,100,405 ("McLaren"). Applicant respectfully traverses this rejection.

McLaren is limited to a locking cap having a helically threaded body, such that the locking cap is threaded over the fixation rod. The rotation of a locking cap over a threaded rod often requires precise alignment of the locking cap to start the rotation process. Moreover, any uneven rotation usually results in the inability to continue to screw the cap, damage to the threads or the need to reverse the cap and start the process over again. The process of rotating the cap also takes extra time, extra hands, extra coordination and extra devices. The process of inserting the McLaren device and rotating the cap may also damage the surrounding tissue or pathology, thereby increasing the likelihood of infection.

The McLaren device also does not allow for extra tensioning of the fixation device by further pulling a wire or using a spring to continuously pull on the wire (e.g., paragraph [0030]), as set forth in the presently claimed invention. While the excess portion of the rod may be removed, the rigid nature of the McLaren rod would require a hacksaw or other cumbersome tool which would increase the time and skills needed for the procedure, along with decreasing the sterility of the process (e.g., the metal shavings distributed from the sawing process).

The McLaren device also requires different sized rods and caps. As such, the McLaren device would literally destroy the benefits and functionality of the presently claimed invention. As set forth in the Background section of the present application, one purpose of the present invention is to avoid the need for numerous cap and rod sizes, along with avoiding the need for managing large sets of caps and rods that need to constantly be replaced. Accordingly, McLaren does not teach or disclose at least "receives a flexible wire having a first end and a second end, wherein said first end of said flexible wire is affixed to a head component, said flexible wire having a first interface along at least a portion of said flexible wire, wherein said first interface includes a sawtooth configuration, wherein said head component attaches to a first object, said cap device mates with said second end of said flexible wire," as recited by amended independent claim 14.

Dependent claims 15-16 variously depend from independent claim 14, so Applicant asserts that claims 15-16 are differentiated from the cited reference for the same reasons as set forth above, as well as in view of their own respective features.

The Examiner rejects claims 1, 3, 4, 6, 8, 11, 12, 17, 18, 20, 21 and 25 under 35 USC § 102(b) as being anticipated by Cachia, U.S. Patent No. 5,893,850 ("Cachia"). Applicant respectfully traverses this rejection.

The Cachia patent discloses a bone fixation device for connecting bones or bone fragments. However, the Cachia disclosure is limited to a single pin with (i) expanding lever arms which are compressed during insertion through the entire bone, then the lever arms expand after exiting out of the other side of the bone; and, (ii) an anchor which rotates around the threads on the other end of the pin.

The Cachia pin is a set length, so the hospital would be required to keep many different pin lengths available. In contrast, the presently claimed invention uses a flexible wire that is cut to the desired length, thereby reducing the need for storing multiple lengths. Moreover, the presently claimed invention does not include rotational threads for rotating an anchor, and instead, includes a cap which translates over the flexible wire.

Furthermore, the Cachia lever arms are mechanical which include the obvious mechanical failures and the extension through the entire surface of the bone includes obvious discomfort issues for the patient, susceptibility to being hit or moved, longer surgery times and infection issues. In contrast, the presently claimed invention does not extend through the entire surface of the bone which minimizes or eliminates many of the disadvantages of the Cachia device. Accordingly, Cachia does not disclose or suggest at least a "flexible wire", "said head component inserted into, and terminating within, one of said objects," nor "said cap is configured to translate along said wire," as similarly recited by independent claims 1, 11 and 17.

Applicant asserts that dependent claims 3, 4, 6, 8, 12, 18, 20, 21 and 25 variously depend from independent claims 1, 11 and 17, so claims 3, 4, 6, 8, 12, 18, 20, 21 and 25 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner rejects claims 11-13 and 17-21 under 35 USC § 102(e) as being anticipated by Dakin, U.S. Patent No. 6,368,326 ("Dakin"). Applicant respectfully traverses this rejection.

The Dakin device is limited to a bone fixation device which includes a cord lock having a threaded member received into the bore of one of a plurality of fasteners. The presently claimed invention does not include rotational threads for locking in the flexible wire into an anchor, and

instead, includes a cap which translates over the flexible wire. The benefits of a cap that translates over the wire, without rotation, are significant. For example, rotation is more likely to disrupt the fixation and introduce (by spiral action) infection and other undesirable products into the bone. Accordingly, Dakin does not disclose or suggest at least “a cap which mates with said second end of said flexible wire by translating along said flexible wire,” as similarly recited in independent claims 11 and 17.

Applicant asserts that dependent claims 12-13 and 18-21 variously depend from independent claims 11 and 17, so claims 12-13 and 18-21 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner rejects claims 14-16 under 35 USC § 102(e) as being anticipated by Gleason, et al., U.S. Patent No. 6,656,185 (“Gleason”). Applicant respectfully traverses this rejection.

Gleason is limited to a simple threaded clip for holding two ends of a surgical cable. The Gleason includes a threaded member received into the bore of a fastener clip. The presently claimed invention does not include rotational threads for locking in the flexible wire into an anchor, and instead, includes a cap which translates over the flexible wire. The benefits of a cap that translates over the wire, without rotation, are significant. For example, rotation is more likely to disrupt the fixation and introduce (by spiral action) infection and other undesirable products into the bone. Accordingly, Gleason does not disclose or suggest at least “such that said cap is configured to translate along said flexible wire,” as recited in independent claim 14.

Dependent claims 15-16 variously depend from independent claim 14, so Applicant asserts that claims 15-16 are differentiated from the cited reference for the same reasons as set forth above, as well as in view of their own respective features.

The Examiner next rejects various claims under 35 USC § 103(a) as being unpatentable over various cited references. Applicant respectfully traverses these rejections. Applicant asserts that the present claims are differentiated from the various 103 combinations of cited references for the same reasons as set forth above for differentiating the independent claims, in addition to their own respective features.

Applicant respectfully submits that the pending claims are in condition for allowance. The Commissioner is hereby authorized to charge any fees, which may be required, or credit any overpayment, to Deposit Account No. **19-2814**. Applicant invites the Examiner to telephone the

undersigned, if the Examiner has any questions regarding this Reply or the present application in general.

Respectfully submitted,

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